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SUBJECT: U.S.-EU HIGH LEVEL REGULATORY FORUM MEETS IN BRUSSELS

¶1. (SBU) SUMMARY: EU and U.S. officials covered a packed agenda during a well-attended High-Level Regulatory Cooperation Forum (HLRCF) in Brussels on July 24. The European Commission hosted this, the sixth HLRCF, gathering regulators from both sides of the Atlantic to discuss regulatory cooperation, including new ideas and advances, and to update private stakeholders on joint progress. Presenters noted progress on issues such as risk assessment, standards, and import safety, and examined regulatory issues around energy technology cooperation and nanotechnology development. In the afternoon, Business Europe hosted a public stakeholder session featuring panel discussions on energy efficiency, counterfeiting and consumer protection. END SUMMARY.

BACKGROUND

¶2. (SBU) This was the first Forum involving Obama administration officials; the 12-member U.S. delegation from Washington, led by Michael Fitzpatrick, Associate Administrator for OMB's Office of Information and Regulatory Affairs (OIRA), was joined by 12 U.S. Mission officials for discussions with over 25 European Commission officials, led by Enterprise Director General Heinz Zourek. Participants briefed on U.S. and EU regulatory reform efforts and priorities, including new U.S. emphasis on openness and transparency and consideration of recommendations for a new presidential executive order on regulatory review, as well as continued EU implementation of its programs on simplification and reduction of administrative burdens.

¶3. (SBU) Participants reviewed ongoing work on impact assessment, standards in regulation, risk assessment and import safety. Both sides discussed regulatory issues around deepening energy technology cooperation and efforts to address rapid nanotechnology development, agreeing to prepare inventories/status reports on both issues for the Fall Transatlantic Economic Council (TEC) meeting. Officials also agreed to pursue another Forum meeting to be held just prior to the Fall TEC. The officials briefed a large group of business and consumer stakeholders in the afternoon on the discussions and participated on issue panels.

¶4. (SBU) U.S. agencies represented included the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Department of Homeland Security/Customs and Border Protection (CBP), the Department of Energy (DOE), the Department o H@mmitmenQf Americans and to econity, all important elemeHLRCF agenda. He described the initial customary review of ongoing regulatory actions at the start of a new Administration, and outlined the regulatory review currently underway by order of the President. He explained that OMB solicited public comments to inform the development of its recommendations for a new presidential Executive Order on regulatory review, eliciting 185 submissions from the public. The recommendations are under review, with a new Executive Order expected to be issued within the next few months. Fitzpatrick emphasized, however, that while this broad regulatory review runs its course, the Washington regulatory process was moving "full steam ahead," with new proposals under development.
¶6. (SBU) Fitzpatrick stressed the Administration's commitment to open government and transparency, highlighting a range of new Web tools for the public to gain information about and participate in the U.S. regulatory process. These include sites such as

www.regulations.gov , which contains over two million documents, including proposed and final rules, public comments, and supporting documents; www.business.gov, an official business link to the USG which also hosts an online community for business to share questions, answers, and best practices; www.data.gov, a searchable site populated by data sets from across the USG and updated regularly; and www.recovery.gov, which allows readers to track stimulus and recovery act funds as they move through the system. He

said the USG will continue to use the Federal Register process for public comment purposes, but also noted the Administration's groundbreaking use of blogs and other web-based technologies to get input on the regulatory process from new and different stakeholders. Fitzpatrick encouraged Commission interlocutors to participate in U.S. public comment processes, saying these are open to all stakeholders.

¶7. (SBU) Marianne Klingbeil, Director within the EU Secretariat General responsible for impact assessment, provided an update on the EU's Better Regulation drive. She said the Commission's Simplification Program, a comprehensive program of simplifying existing regulations, is one key component, complemented by the Administrative Burden Reduction Program, with a goal of reducing the costs to business of administrative burdens 25 percent by 2012. She added that the Commission's online consultation is also open to third country comments.

¶8. (SBU) Georgette Lalas, Director at DG Enterprise for consumer goods, foods and pharmaceuticals, said that U.S.-EU cooperation on pharmaceuticals, medicines and cosmetics regulation is strong. She emphasized DG ENTR's good relations and frequent discussions with the U.S. FDA in all of these areas. She added that the EU is working to rationalize its current large number of auto safety regulations. Lalas, whose division also covers the automotive industry, also commented that cooperation with the National Highway Transport Safety Administration is less active, despite the recent conclusion of a Memorandum of Understanding.

¶9. (SBU) Bernd Langeheine, Director at DG Information Society for electronic communications policy, reviewed DG INFSO's efforts to facilitate ambitious EU plans to extend broadband coverage across the 27 Member States and to help Member States manage their transition (at different times) from analogue to digital TV broadcasting. DG INFSO's goal is to keep Member States focused on service and technology neutrality as a basic principle during this transition. In this respect, he said, DG INFSO followed closely the successful June analogue to digital switchover in the U.S. He also updated participants on the EU's extensive telecoms reform package, which has passed through much of the EU legislative process but will undergo conciliation in the fall. When adopted, he said, the reform will establish the "nucleus" of a single EU telecoms regulatory authority that will take the EU another step toward a true single market for telecommunications.

IMPACT ASSESSMENTS

¶10. (SBU) Klingbeil said that the EU is continually striving to improve its impact assessment process, and reminded the Forum that the EU evidence-based approach was applied "at the beginning of the legislative process" and allowed policy makers in the Commission to evaluate "different impacts with different options". She noted that impact assessment guidelines were revised and improved in January ¶2009. She said that, though an impact assessment should be done on major amendments under terms of an agreement with the European Parliament (EP) and the EU Council (member states), this was not always followed in practice. On quality control, Klingbeil said the EU Impact Assessment Board sent back one-third of all impact assessments done in 2008 because they were not good enough, and she expected that record to improve.

¶11. (SBU) In terms of ongoing HLRCF initiatives, Klingbeil noted continuing cooperation between OMB/OIRA and the Impact Assessment Board. She said it would be interesting to explore further an integrated approach to impact assessment that incorporates economic, environmental, and social impacts. She added that it also would be useful to compare notes on impacts on Small and Medium Enterprises (SMEs), an area that needs more study, particularly given that SMEs account for 95 percent of all EU companies. Finally, Klingbeil said impact assessments and health might provide another area for U.S-EU discussion and potential collaboration.

¶12. (SBU) Alex Hunt from OMB/OIRA provided an update on OMB's request for public comments on draft guidance to agencies on the type of analysis needed to assess international trade and investment impacts. The draft guidance was released as part of OMB's 2008

draft Report to Congress on the Costs and Benefits of Federal Regulation. In January 2009, OMB released the final Report to Congress, in which OMB responded to the public comments on this draft guidance. Although OMB received supportive public comment, due to the pending change in Administration, OMB did not feel it would be appropriate to formally incorporate the international trade

guidance into Circular A-4 or other official agency guidelines. Hunt said the process for developing a new Executive Order on regulatory review might change the way U.S. impact analysis is conducted. In the meantime, OMB has encouraged agencies to refer to the discussion in the Report for a useful framework for satisfying their existing obligations to consider the international impacts of proposed and final regulations, and carefully evaluate concerns that new U.S. rules could act as nontariff barriers. He agreed that the U.S. would also be interested in looking at the impact of regulation on SMEs.

STANDARDS

¶13. (SBU) On standards, Pedro Ortun, Director at DG Enterprise, recalled that the October HLRCF had requested that the U.S. and EU prepare papers on our respective uses of international standards in regulation. He said the EU contribution would be finished in time for a fall Forum. He noted that in the paper, the Commission will examine different approaches to standards in regulation. He said the Commission had just published a White Paper on ICT standardization, the public comment period for which was nearly finished. This would provide input into a Commission deep review of standards. Ortun added that the Commission would discuss a draft of this broader report at an October 14 conference in Brussels, with a final version due early 2010.

¶14. (SBU) OIRA's Hunt said that the Department of Commerce has drafted a paper on the role of standards in the rule-making process and that an exchange of papers could promote mutual understanding. He said the U.S. paper provides a detailed overview of the U.S. regulatory process, the policy and legal context for the use of standards in support of regulation and procurement, as well as the various ways standards are referenced in U.S. regulations. Hunt added that he looked forward to reviewing a Commission paper on standards and said an exchange of views on the respective U.S. and EU papers might be an agenda item for a fall HLRCF. Jonathan Farnell of DG ENTR suggested that both sides should share their papers in September, and prepare a cover note on similarities, differences and challenges in their respective systems prior to the fall Forum. Hunt agreed that a jointly drafted introduction to the U.S. and EU papers on their respective approaches to standards would be useful.

RISK ASSESSMENT

¶15. (SBU) Panagiotis Daskaleros of DG SANCO emphasized his directorate's long cooperation with OMB/OIRA and the fruitful dialogue between scientists on risk that has been underway since ¶2007. He noted that rising interdependence and globalization "means we have to work together on risk, especially on new and emerging technologies and the challenges that arise from them." Daskaleros said SANCO and OMB agreed to work together on three broad areas moving forward: exposure assessment, including how to incorporate new technologies into the assessments; risk assessment terminology and characterization; and emerging risks. (Note: The area of emerging risks may include a joint analysis of past crises to gather lessons learned from how those emerging risks were assessed and also an evaluation of how we can use new state of art "avant garde" technologies such as toxicogenomics and systems biology to inform adverse effects in risk assessments. End note). Daskaleros said collaboration should be guided by a commitment to avoid duplication and should be forward looking, while learning from past experience. OMB's Nancy Beck agreed with Daskaleros' comments, noting that U.S. scientists are very enthusiastic about cooperation with Europe on risk assessment.

IMPORT SAFETY

¶16. (SBU) Jeffrey Shuren, FDA Associate Commissioner for Policy, briefed on FDA's expanding pharmaceutical joint inspection program with the EU. He noted FDA's placement of officials in Brussels and at the European Medicines Agency in London to facilitate deeper cooperation, and FDA's plans to launch a similar exchange with the European Food Safety Agency. He reviewed closer bilateral work on

drug development, orphan diseases, cosmetics and tobacco, and FDA interest in increasing cooperation on medical devices as well, to avoid duplicate inspections. Shuren stressed the Administration's high priority on food safety, highlighted by the establishment of a

cabinet-level working group on food safety and proposals for a modernization of U.S. food safety laws. USEU CBP Attache David Dolan reviewed CBP's increasing focus on import safety, noting joint enforcement operations and work in the Joint Customs Cooperation Committee (JCCC) and World Customs Organization (WCO).

¶17. (SBU) Ortun of DG ENTR lauded useful bilateral cooperation with the Consumer Product Safety Commission on toy safety, including such items as magnetic toys and childrens' books, and over testing methods. Daskaleros of SANCO reiterated some of this, but also commented on cooperation in the area of product traceability.

FUTURE DIRECTIONS IN REGULATORY COOPERATION

¶18. (SBU) Forum participants then turned to discussion of finding common ground in regulation of emerging technologies such as new energy technologies and nanotechnology. David Rodgers, Director for Strategic Planning and Analysis, in the Office of Energy Efficiency and Renewables at DOE, reviewed the increased funding ($45 billion total) the USG is directing toward clean energy technology development in the new budget and stimulus package. He pointed to the June DOE rulemaking to phase out incandescent lightbulb usage in the U.S. by 2012, which will save four quadrillion BTUs in U.S. energy use. He highlighted key areas of cooperation with Europe, including on development of biofuels, batteries and efficiency standards. Jim Jones, of the Office of Prevention, Pesticides and Toxic Substances at EPA, reviewed longstanding U.S.-EU cooperation on the U.S. Energy Star efficiency standards program, and growing cooperation on green building standards.

¶19. (SBU) Didier Herbert of DG Enterprise previewed the Commission Green Paper, expected for the end of 2009, on promoting energy technology development in the EU. This will be accompanied by a strategic paper on innovation, he said. He discussed the EU directives on ecodesign and efficiency labeling, which cover lighting, motors, refrigerators and other products. He noted the four drivers for the EU emphasis on new environmental industries: to promote EU growth, innovation and competitiveness; to enhance sustainability; as an exit strategy from the current economic crisis; and to lead the way toward larger global solutions to climate change and sustainability problems. John Farnell then proposed, and Michael Fitzpatrick agreed, that both sides should complete an inventory/map of bilateral energy technology performance standards and areas of potential cooperation for the TEC, including identification of areas for future cooperation.

¶20. (SBU) Sally Tinkle, of the National Institute of Environmental Health Sciences at NIH, discussed the U.S. National Nanotechnology Initiative, a 10-year old interagency group (27 agencies) coordinating USG nanotechnology activity, including to: develop new technologies for commercial and societal benefit; develop nanotechnology infrastructure that encompasses standards, terminology metrics and a skilled workforce; and ensure responsible development of nanotechnology to maximize benefit and minimize risk to public health and safety.

¶21. (SBU) Lalas of DG Enterprise explained that the Commission is preparing a 2010-15 nanotechnology management plan. She said the Commission had examined whether the existing EU regulatory framework sufficed to manage emerging nanotechnologies, and concluded that different sectors are doing adequate risk assessment. No single framework can cover all sectors, she noted. That said, she emphasized that the precautionary principle is particularly relevant in the area of new technologies, noting that in the absence of environmental and safety data, it would be difficult to approve products. The EU needs to fine-tune existing legislation, not completely overhaul it, she concluded.

¶22. (SBU) A DG Environment representative noted that cooperation over nanotechnology approaches has been difficult, however, with OECD work, for example, not keeping pace with the worldwide dissemination of nanotechnologies. This cooperation seems limited by industry and government resource commitments, he added. Farnell, alluding to the precautionary principle issue, agreed that the Commission sees some differences in U.S. and EU approaches, and suggested that the HLRCF prepare a report for the TEC mapping and identifying similarities and differences. Fitzpatrick agreed this would be valuable.

¶23. (SBU) Finally, Farnell proposed that the Forum could prepare a

report on how mutual recognition might help the overall goal of increasing long-term U.S.-EU economic integration. He suggested that a Forum paper discussing possibilities and constraints over the use of mutual recognition for bilateral regulatory frameworks, could be ready to present to the TEC by spring 2010. Hunt of OMB/OIRA agreed this could be useful, suggesting that such a paper review the history of Mutual Recognition Agreements (MRAs), and in particular assess the lessons learned from previous U.S.-EU MRAs. Hunt also suggested that the Forum should focus on specific sectors, since this approach has generally been proven easier to negotiate and implement. USEU EMIN Chase noted that some agencies had taken potentially more useful, broader approaches, as with the Securities Exchange Commission's notion of findings on "compatible regulatory regimes". Farnell promised to provide the U.S. team a more detailed proposal on the issue.

BRIEFING PUBLIC STAKEHOLDERS

¶24. (U) The afternoon of July 24, leading U.S. and EU Forum participants briefed over 100 business and consumer stakeholders on the morning's discussions. Hans Glatz, Chair of Business Europe's U.S. network, welcomed the Forum participants, noting private sector commitment to regulatory cooperation discussions and the TEC process overall. Glatz stressed the value of these dialogues in promoting joint U.S.-EU efforts to recover from the financial crisis and fight creeping protectionism.

¶25. (SBU) In a novel approach to the HLRCF de-brief sessions, business and consumer representatives then made panel presentations on "Counterfeiting and Import Safety," and on "Regulatory Impacts on Deployment of New Energy Technologies," with U.S. and EU officials serving as respondents. Business reps, including Bill Kovacs, Senior Vice President of the U.S. Chamber of Commerce for Environment, Technology and Regulatory Affairs, emphasized the need to strengthen IPR protection to fight counterfeiting, improve import safety and promote energy innovation. Willemien Bax, Deputy DG for the European Consumer Organization, said IPR enforcement efforts should focus on dangerous products first, and supported development of common standards to promote clean energy technologies.

¶26. (U) Michael Fitzpatrick, Associate Administrator for OMB's Office of Information and Regulatory Affairs (OIRA), has not cleared this cable.

CHASE